

REMARKS

Status of the Claims

Claims 1, 5-9, and 13-22 are pending in the present application. Claims 2 and 10 were previously cancelled. Claims 3-4 and 11-12 are presently cancelled. Claims 6, 14, and 18-21 are withdrawn as directed to a non-elected invention. Claims 1 and 9 are amended to specify a "MHC class I-restricted" T cell receptor gene. Support for this amendment is found, for example, in claims 3 and 11, now canceled. Claims 1 and 9 are further amended to clarify that the described cells are isolated from leukocytes. Support for this amendment is found, for example, on page 7 of the originally filed application. Claims 5, 7, 13, and 15 are also amended to depend solely from pending claims. No new matter is added by way of this amendment. Reconsideration is respectfully requested.

Issues under 35 U.S.C. § 103(a)

Claims 1, 3, 4, 7-9, 11, 12, 15-17, and 22 remain rejected under 35 U.S.C. § 103(a) as allegedly obvious over Kessels *et al.*, *Nature Immunology*, 2:957-961, ("Kessels") in view of Fujio *et al.*, *Journal of Immunology*, 165:528-532, ("Fujio"), Tsuji *et al.*, *Cancer Science*, 2003, 94:389-393, ("Tsuji"), and Nishimura, *Cancer Treatment and Host*, 12:363-373, ("Nishimura"), *see Final Office Action*, pages 2-7. For the reasons set forth below, Applicants respectfully traverse.

Claims 1, 5, 9, and 13 are also rejected under 35 U.S.C. § 103(a) as allegedly obvious over Kessels, Fujio, Tsuji, and Nishimura, and in view of U.S. Patent No. 7,323,181 to Gaiger *et al.*, ("Gaiger"), *see Final Office Action*, pages 8-11. For the reasons set forth below, Applicants respectfully traverse.

In the Advisory Action, the Examiner states that the claims read on a process of preparing cells for cell therapy and imparting antigen specificity to the Th1 cells and Tc1 cells by transducing the Th1 cells and the Tc1 cells with a TCR gene that recognizes a cancer associated antigen. The Examiner reiterates that whether the Th1 cells or Tc1 cells are induced or activated does not appear to be relevant to the instant invention.

Applicants submit that the amended claims are not rendered obvious by the cited references. The present invention, as defined in the amended claims, is characterized in that

tumor antigen-specific helper T1 cells can be obtained by transducing isolated helper T1 cells with a MHC class I-restricted T cell receptor gene.

Applicants reiterate that the purpose of the present invention is not to obtain Tc cells, nor to obtain helper T1 cells that express the MHC class II-restricted TCR. Accordingly, such cells, as disclosed in the prior art, are not encompassed by the present claims. As noted above, the claims specify that tumor antigen-specific helper T1 cells can be obtained by transducing isolated helper T1 cells with a MHC class I-restricted T cell receptor gene. For the reasons set forth above and in the response filed on May 12, 2011, the cited references do not teach or suggest this feature.

Moreover, Applicants submit that an ordinary artisan would not have attempted to use the method of the present invention with a reasonable expectation of success.

Further Applicants note that the Examiner reiterates that "whether the Th1 cells or Tc1 cells are induced or activated or not appears to be irrelevant in the instant application." Applicants reiterate that this position is inconsistent with the general knowledge of the art, *see* May 12, 2011, response.

In view of the foregoing, the claims are not rendered obvious by the cited references. Withdrawal of the rejection is respectfully requested.

CONCLUSION

In view of the above amendments and remarks, Applicants believe the instant application is in condition for allowance.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Linda T. Parker, Ph.D., Registration No. 46,046, at the telephone number of the undersigned below to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Director is hereby authorized in this, concurrent, and future replies to charge any fees required during the pendency of the above-identified application or credit any overpayment to Deposit Account No. 02-2448.

Dated: JUL 12 2011

Respectfully submitted,

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